EDITORIAL

CONSORT STATEMENT

Vishal R. Tandon, Annil Mahajan*, Sudhaa Sharma, S.K Gupta*****

JK Science, Journal of Medical Education and Research is progressing rapidly with many achievements to its credit recently. The number of subscriptions, submission of articles and indexing status has increased manifold and every effort is being taken to improve the quality of journal which depends on quality of published articles, in turn on quality of research methodology adopted by contributors. The present editorial on the concept of CONSORT statement is an attempt to continuously educate new authors/researchers & postgraduates students regarding research methodology as a commitment on the part of JK Science in continuation to our previously published editorials (1, 2).

CONSORT (3) is consolidated standards of reporting trials. To comprehend the results of a randomized controlled trial (RCT), readers must understand its design, conduct, analysis and interpretation. This goal can only be achieved through complete transparency from authors and hence, the CONSORT statement as a research tool was developed to help authors improve reporting of randomized clinical trial by using a checklist and flow diagram. CONSORT also helps readers to assess the strengths and limitations of an RCT and to know the quality of its methodology in a first look at the publication. It also helps editors and reviewers of the journals to quickly analyze the quality of research methodology being adopted by authors which helps in prompt decisions on the articles sumitted for publication.

A comparative before and after evaluation suggest that use of the CONSORT is associated with improvement in the qualitiy of RCTs (4). Even flow diagrams are associated with improved quality of reporting RCTs (5).

Table-1 (Adopted from http://www.consort-statement.org/Statement/ revisedstatement.htm)

TITLE & ABSTRACT	1	As per format of journal
INTRODUCTION		
Background	2	Scientific background and explanation of rationale.
METHODS		
Participants	3	Eligibility criteria & settings & locations.
Interventions	4	Precise details of the interventions intended for each group.
Objectives	5	Specific objectives and hypotheses.
Outcomes	6	Clearly defined primary and secondary outcome measures
Sample size	7	How sample size was determined.
Randomization Sequence generation	8	Method used
Randomization Allocation concealment	9	Method used to implement the random allocation sequence
Randomization Implementation	10	Who generated allocation sequence, who enrolled & assigned participants.
Blinding (masking)	11	Whether or not participants blinded
Statistical methods	12	Used
RESULTS		
Participant flow	13	Flow of participants through each stage (diagram)
Recruitment	14	Dates-periods of recruitment & follow-up.
Baseline data	15	Baseline demographic & clinical characteristics of each group.
Numbers analyzed	16	No. of participants (denominator) & “intention-to-treat”.
Outcomes & estimation	17	For each primary and secondary outcome
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed
Adverse events	19	All important adverse events or side effects in each intervention group
DISCUSSION		
Interpretation	20	Interpretation of the results, taking into account study hypotheses
Generalizability	21	Generalizability (external validity) of the trial findings.
Overall evidence	22	General interpretation of the results in the context of current evidence.

From the Editorial Secretary, *Editor-in-Chief, **Director Editor & ***Managing Editor, JK Science, Journal of Medical Education and Research, Govt. Medical College Jammu-J&K-India.

Correspondence to : Dr Annil Mahajan, Editor in Chief -JK Science, Journal of Medical Education & Research , G.M.C., Jammu-J&K-India.

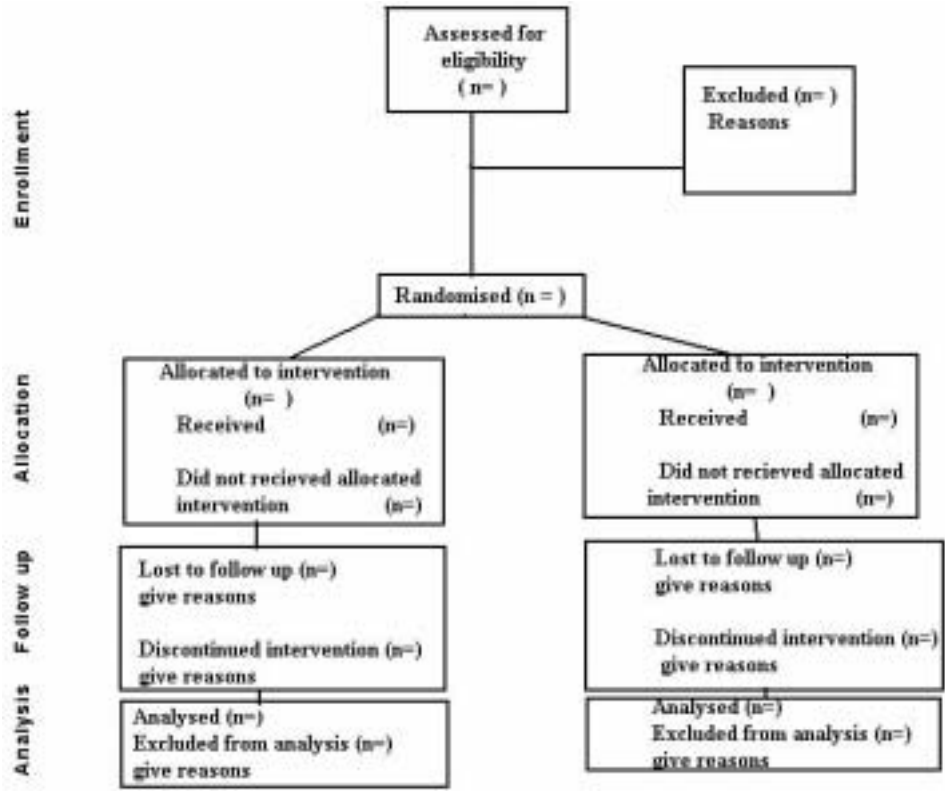

Fig-1 (Adopted from http://www.consort-statement.org/Statement/revisedstatement.htm)

It was developed by an international group of clinical trialists, statisticians, epidemologists and biomedical editors in the mid 1990s and supported by many international journals and world associations of medical editors.

The most recent **CONSORT Statement** includes a 22-item checklist (Tab. 1) and a flow diagram (Fig. 1). The check list includes items based on evidence that need to be addressed in the report and the flow diagram allows readers to observes the manner in which participants are recruited for RCT and provides guidance for various stages such as enrolment, intervention allocation, follow up and analysis.

The use of CONSORT can reduce (if not eliminate) inadequate reporting of RCTs. The adherence to the CONSORT statement has a critical value to researchers, health care providers, peer reviewers, journal editors and health care providers and guarantees integrity of reported results of researchers. Editorial team of JK Science strongly emphasize to authors/contributors to adopt CONSORT statement while reporting RCTs. We are also encouraged with the evolving importance of it to include its reference in our Instructions to Contributors. Please join hands in propogating this new inclusion as another step towards improvement of Medical Journalism and in turn JK Science.

References

1. Gitanjali B. Training Students in Research Methodology: Are We Doing Enough? *JK Science* 2006; 8(1):1-3
2. Tandon VR, Mahajan A, Sharma S, Gupta SK. Unethical Publication Practices. *JK Science* 2006;8(3):123-124
3. Moher D, Schulz KF, Altman DG. Consensus statement. The CONSORT Statement: revised recommendations for improving the quality of reports of parallel group randomised trials. *BMC Med Res Methodology* 2001; 1: 2.
4. Moher D, Jones A, Lepaze L *et al.* Use of the CONSORT statement and quality of reports of randomized trials. *JAMA* 2001 ; 285 : 192-95.
5. Egger M, Juni P, Barilett C *et al.* Value of flow diagram in reports of RCT. *JAMA* 2001 ; 288 : 1996-99.